UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,361	09/16/2003	Stephen P. Dretler	61417.123 US2	1651

23483 7590 02/25/2005

WILMER CUTLER PICKERING HALE AND DORR LLP
60 STATE STREET
BOSTON, MA 02109

EXAMINER	
MENDOZA, MICHAEL G	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,361	DRETLER ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,14-16,18,20-27 and 29-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 14-16, 18, 20-27, and 29-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 26 November 2004 have been fully considered but they are not persuasive. The Applicant argues that the device of Chuttani et al. does not taper. As seen in the below drawing, the device does taper.

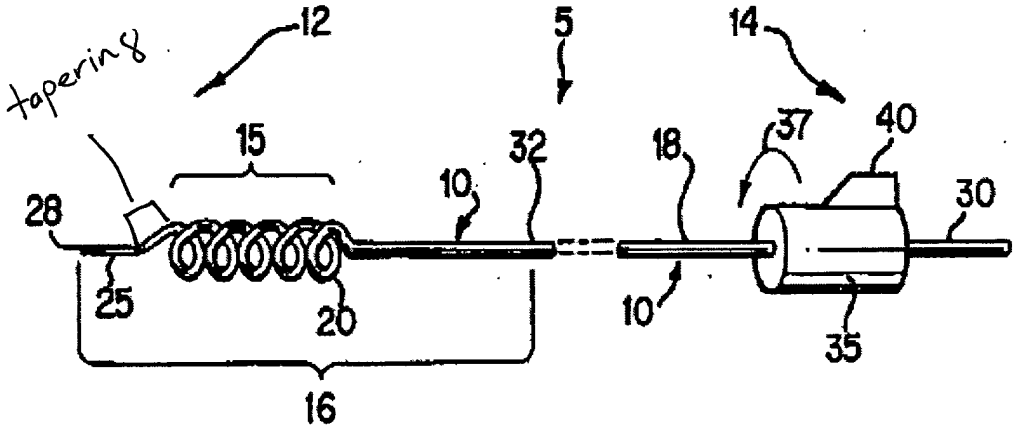

FIG. 1

2. The Applicant also argues that Fina does not teach lithotripsy. Fina does teach the method of lithotripsy as stated in col. 1, lines 17-20. Fina also teaches it is know in the art to use different types of lithotripsy (col. 1, lines 49-56).

3. The Applicant further argues that Fina fail to teach the device of claim 18. The Applicant states that "the conical-shaped element (10) is an additional anode electrode". Fina teaches that the anode electrode 10 can be used alone without anode electrode 4. In order for the electode 10 to be used alone, it must inherit the same properties as electrode 4. Therefore it must be able to contract into sleeve 2 and expand when it protrudes (col. 4, lines 50-54). Therefore, electrode 10 would be made of a "super-elastic deformable material".

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 14, 18, 20, 29, 30-39, 42-45 and 48-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Chuttani et al. 5054501.

5. Chuttani et al. teaches a medical device comprising a generally longitudinally-extending wire core, a portion of the core forming a helical coil which tapers in diameter from a lager diameter to a smaller diameter (col. 3, lines 20-24), at least the portion of the core forming the helical coil being made of a super-elastic deformable material, wherein the core comprises a super-elastic deformable material; a flexible tubular sheath 50; the sheath having an inner diameter that is greater than the diameter of the guidewire other than a portion of the guidewire forming the helical coil, such that coil deforms into a configuration having a maximum diameter not more than the inner diameter of the sheath upon retraction into the sheath and return to a coil configuration having a maximum diameter greater than the outer diameter of the sheath upon withdrawal from the sheath (figs. 1-3);; wherein a layer of polymeric material substantially covers at least the portion of the core forming the helical coil; wherein a layer of polymer material substantially covers the outer surface of the wire core; wherein the polymeric material comprises a fluorinated polymer; wherein the fluorinated polymer

is polytetrafluorethylene (col. 4, lines 21-30); wherein the wire core is about 50 cm to about 250 cm long; wherein the wire core is about 140 cm to about 220 cm long; wherein the wire core is about 0.015 inches (0.381 mm) to about 0.04 inches (1.016 mm in width) (see claim 2); wherein the proximal end of the helical coil has a diameter of about 0.2 cm to about 3.0 cm; wherein the proximal end of the helical coil has a diameter of about 0.5 cm to about 1.5 cm; wherein the proximal end of the helical coil has a diameter of about 0.7 cm to about 0.8 cm (see claim 8); wherein the helical coil comprises between about 5 and about 15 turns (fig. 1).

6. Chuttani et al. teaches a medical procedure comprising the steps of: providing a medical device in a configuration in which the helical coil of the guide wire of the device is retracted into the tubular sheath of the device', introducing the device in the configuration into a desired pathway within a body; positioning the device in a desired location with the pathway; moving the helical coil portion of the guidewire relative to the sheath such that the helical coil portion of the guide wire is withdrawn from the sheath and returns to a coil configuration and in which the coil engages the inner surface of the pathway (figs. 1-3).

7. Claims 18 and 20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Fina 6248113.

8. Fina teaches a medical procedure comprising the steps of: providing a medical device according to claim 18 (fig. 6) in a configuration in which the helical coil of the guide wire of the device is retracted into the tubular sheath of the device; introducing the device in the configuration into a desired pathway within a body; positioning the device

in a desired location with the pathway; moving the helical coil portion of the guidewire relative to the sheath such that the helical coil portion of the guide wire is withdrawn from the sheath and returns to a coil configuration an in which the coil engages the inner surface of the pathway (fig. 13); wherein a biological calculus is with the pathway and the procedure includes fragmentation of the calculus, including the steps of: locating the biological calculus within the pathway; placing at least a portion of the sheathed guidewire beyond the location of the calculus; and moving the guidewire relative to the sheath such that the helical coil portion thereof is exposed from the distal end of the sheath and reforms into a helical coil configuration distally of the calculus; wherein the procedure further comprises the step of fragmenting a biological calculus located in a desired location in the pathway and distally to the coil that has engaged the inner surface of the pathway (col. 5, lines 1-20), using lithotripsy; wherein the lithotripsy comprises one of electrohydraulic, pneumatic pulse, acoustic shock wave, and laser lithotripsy (col. 1, lines 49-56).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 40, 41, 55, 56, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chuttani et al.

11. Chuttani et al. discloses the claimed invention except for wherein the distal end of the helical coil is about 2 cm to about 50 cm from the distal end of the device, or wherein the distal end of the helical coil is about 10 cm to about 24 cm from the distal end of the device. It would have been an obvious matter of design choice to use the claimed limitations, since the Applicant has not disclosed that the claimed limitations solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the distal tip 25 of the device.

12. Chuttani et al. discloses the claimed invention except for wherein the coil portion of the guidewire fits intot the flexible tubular sheath having an inner diameter about 0.005 inches greater than the coil prior of the guidewire. It would have been an obvious matter of design choice to use the claimed limitations, since the Applicant has not disclosed that the claimed limitations solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with device shown in fig. 2.

13. Claims 15, 16, 24-27, 46, 47, and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chuttani et al. in view of Samson et al. 6066149.

14. Chuttani et al. teaches the device of claim 1. It should be noted that Chuttani et al. fails to teach wherein the super-elastic deformable material is an alloy comprising nickel and titanium or nickel, titanium, and chromium.

Samson et al. teaches a device with a common alloy comprising nickel and titanium or nickel, titanium, and chromium (col. 6, lines 48-58). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made

to use an alloy comprising nickel and titanium or nickel, titanium, and chromium because the use of such alloys are old and well know in the art as super-elastic alloys for use within a body.

15. Chuttani/Samson teaches the device of claims 1 and 18 wherein at least a portion of the device includes a layer of radiopaque material comprising gold, platinum, tantalum, tungsten, iridium, rhodium, rhenium, or an alloy of two or more radiopaque materials (col. 6, lines 42-48).

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 13 and 14 of U.S. Patent No. 6620172. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claim is merely broader than the patent claim. The structural limitations set forth in claims 1 and 24 of the instant application are also claimed in the patent, e.g., a medical device comprising a generally

longitudinally-extending wire core, a portion of the core forming a helical coil which tapers in diameter from a larger diameter to a smaller diameter, at least the portion of the core forming the helical coil being made of a super-elastic deformable material; and a portion of the coil is covered with a radiopaque material.

18. Claims 15, 16, 20, and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 13, and 14 of U.s. patent No. 6620172 in view of Samson et al. 6066149. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claim merely adds a feature absent from the patent claim. The structural limitations set forth in claims 1 and 13 of the instant application are also claimed in the patent, e.g., a medical device comprising a generally longitudinally-extending wire core, a portion of the core forming a helical coil which tapers in diameter from a larger diameter to a smaller diameter, at least the portion or the core forming the helical coil being made of a super-elastic deformable material.

19. The difference between claims 15 and 16 of the instant application and claims 1 and 13 of the patent is the limitation of the super-elastic deformable material is an alloy comprising nickel and titanium or nickel, titanium, and chromium.

20. Samson et al. discloses a device comprising an alloy comprising nickel and titanium or nickel, titanium, and chromium (col. 6, lines 48-58).

21. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use an alloy comprising nickel and titanium or nickel, titanium, and chromium because the use of such alloys is old and well know in

the art as super-elastic alloys for use within a body.

22. The difference between claims 20 and 27 of the instant application and claims 1, 13, and 14 of the patent is the limitation of the radiopaque materials comprises gold, platinum, tantalum, tungsten, iridium, rhodium, rhenium, or an alloy of two or more radiopaque materials.

23. Samson et al. discloses a device comprising radiopaque materials comprising gold, platinum, tantalum, tungsten, iridium, rhodium, rhenium, or an alloy of two or more radiopaque materials (col. 6, lines 42-48),

24. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use radiopaque materials comprising gold, platinum, tantalum, tungsten, iridium, rhodium, rhenium, or an alloy of twp or more radiopaque materials to visualize the position of the device during a procedure.

25. Claim 18 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 7 of U.S. Patent No. 6620172 in view of Chuttani et al. Although the conflicting claims are not identical, they are not paentably distinct from each other because the application claim merely adds a feature absent from the patent claim. The structural limitations set forth in claims 1 and 13 of the instant application are also claimed in the patent, e.g., a medical device comprising a generally longitudinally-extending wire core, a portion of the core forming a helical coil which tapers in diameter from a larger diameter to a smaller diameter, at least the portion or the core forming the helical coil being made of a

super-elastic deformable material; wherein the guidewire includes one or more wrapped helical springs surrounding a longitudinally-extending portion of the core, and a polymeric material covering a major fraction of the outer surface of the springs.

26. The difference between claim 18 of the instant application and claims 1 and 13 of the patent is the limitation of the a flexible tubular sheath', the sheath having an inner diameter that is greater than the diameter of the guidewire other than a portion of the guidewire forming the helical coil, such that coil deforms into a configuration having a maximum diameter not more than the inner diameter of the sheath upon retraction into the sheath and return to a coil configuration having a maximum diameter greater than the outer diameter of the sheath upon withdrawal from the sheath.

27. Chuttani et al. teaches a flexible tubular sheath; the sheath having an inner diameter that is greater than the diameter of the guidewire other than a portion of the guidewire forming the helical coil, such that coil deforms into a configuration having a maximum diameter not more than the inner diameter 6f the sheath upon retraction into the sheath and return to a coil configuration having a maximum diameter greater than the outer diameter of the sheath upon withdrawal from the sheath (see figs. 1-3).

28. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a flexible tubular sheath; the sheath having an inner diameter that is greater than the diameter of the guidewire other than a portion of the guidewire forming the helical coil, such that coil deforms into a configuration having a maximum diameter not more than the inner diameter of the sheath upon retraction into the sheath and return to a coil configuration having a maximum diameter greater

than the outer diameter of the sheath upon withdrawal from the sheath to allow positioning of the device. Furthermore, it is old and well known in the art to use a sheath/catheter for placement of traps, filters, fragmenting means, etc...into a body.

Conclusion

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (571) 272-4694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM

GLENN K. DAWSON
PRIMARY EXAMINER